DOCKET NO: 100051.10611 **PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: **Waldman, Scott A.**

Serial No.: **10/695,578** Group Art Unit: **1642**

Filed: **October 27, 2003** Examiner: **Aeder, Sean E.**

Title: **METASTATIC COLORECTAL CANCER VACCINE**

Commissioner for Patents
P.O.Box 1450
Alexandria, VA 22313-1450

Dear Sir:

DECLARATION OF DR. SCOTT A. WALDMAN

I, Scott A. Waldman, do hereby declare as follows:

1. I am the inventor of the subject matter claimed in the above-identified U.S. Patent Application.

2. I am a Professor at the Thomas Jefferson University, Jefferson Medical College where I have appointments in both the Department of Medicine, Division of Clinical Pharmacology, and the Department of Biochemistry & Molecular Pharmacology.

3. I am co-author of the following published scientific articles:

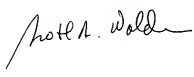
a. Snook, A.E. *et al.* Cancer mucosa antigens as a novel immunotherapeutic class of tumor-associated antigen (2007) Clin Pharmacol Ther. 82(6):734-739, Review., a copy of which is attached hereto as Exhibit A.

b. Snook, A.E. *et al.* Guanylyl cyclase C -induced immunotherapeutic responses opposing tumor metastases without autoimmunity (2008) *Submitted*, a copy of which is attached hereto as Exhibit B.

4. Snook, A.E. *et al.* Cancer mucosa antigens as a novel immunotherapeutic class of tumor-associated antigen (2007) Clin Pharmacol Ther. 82(6):734-739, reports the potential of antigens whose expression is restricted to normal intestinal mucosa and derivative colorectal tumors as a class of immune targets supporting efficacious anti-tumor immunotherapy. The article notes that GCC, whose expression is restricted to normal intestine and derivative tumors, is an ideal candidate for clinical study and includes data in Figure 3 showing results of experiments of GCC-specific anti-tumor immunity in a mouse model. The article reports that the results provide proof of principle.

5. Snook, A.E. *et al.* Guanylyl cyclase C -induced immunotherapeutic responses opposing tumor metastases without autoimmunity (2008) *Submitted*, reports the antitumor efficacy of guanylyl cyclase C (GCC) delivered using a recombinant viral vector to mouse models of metastatic colon cancer. The manuscript reports that immunization with GCC-expressing viral vectors opposed the formation of nascent metastases to liver and lung, and extended the median survival of mice with established lung metastases following therapeutic immunization without autoimmunity.

6. I declare that all statements made herein are of our own knowledge true and statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.



Scott A. Waldman, M.D., Ph.D.

05/03/08
Date

Attachments:

Exhibit A - Snook, A.E. *et al.* Cancer mucosa antigens as a novel immunotherapeutic class of tumor-associated antigen (2007) Clin Pharmacol Ther. 82(6):734-739

Exhibit B. - Snook, A.E. *et al.* Guanylyl cyclase C -induced immunotherapeutic responses opposing tumor metastases without autoimmunity (2008) *Submitted*